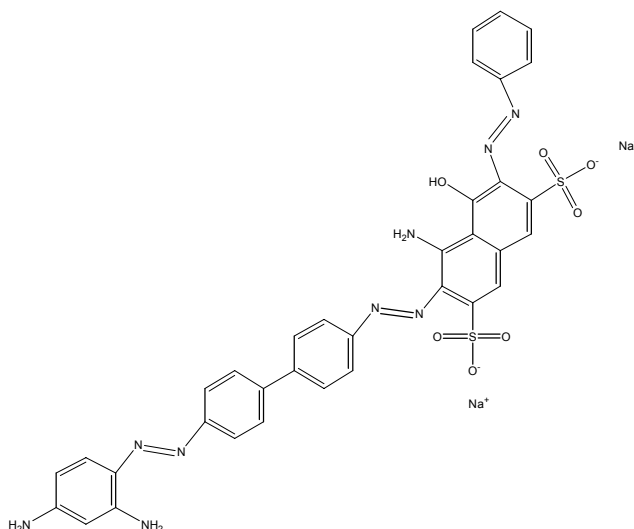


**DIRECT BLACK 38**  
**CAS No. 1937-37-7**

First Listed in the *Third Annual Report on Carcinogens* as *Reasonably Anticipated to be a Human Carcinogen*, updated to *Known to be a Human Carcinogen* in the *Ninth Report on Carcinogens*



**CARCINOGENICITY**

Direct Black 38 is *known to be a human carcinogen* based on the listing of benzidine-based dyes that are metabolized to benzidine as *known to be human carcinogens* in the Report on Carcinogens (NTP, 2000). This listing is based on the following observations: 1) benzidine is a known human carcinogen (IARC V.1, 1972; IARC, S.1, 1979; V.29, 1982; IARC S.7, 1987; and NTP, 1998); 2) metabolism of benzidine-based dyes to release free benzidine is a generalized phenomenon in humans and all experimental animal species studied, (Rinde and Troll, 1975; Lynn et al., 1980; Nony and Bowman, 1980; Lowry et al., 1980; and Martin and Kennelly, 1985); 3) benzidine exposure from exposure to benzidine-based dyes, including Direct Black 38, is equivalent to exposure to equimolar doses of benzidine (Lynn et al., 1980); and 4) all available evidence indicates benzidine-based dyes are animal carcinogens and represent a carcinogenic risk to humans (NCI 108, 1978; IARC, V.29, 1982; IARC S.4, 1982). There are no epidemiology studies available to assess the human carcinogenicity of Direct Black 38 alone.

There is sufficient evidence for the carcinogenicity of commercial Direct Black 38 in experimental animals (IARC V.29, 1982; IARC S.4, 1982; IARC S.7, 1987). When administered in the diet, Direct Black 38 induced hepatocellular carcinomas in male rats and neoplastic nodules of the liver in rats of both sexes. When administered in the drinking water, Direct Black 38 induced papillomas and carcinomas of the urinary bladder, carcinomas of the liver, and adenocarcinomas of the colon in rats. There was no evidence that the compound was carcinogenic in mice when administered by these routes (NCI 108, 1978; IARC V.29, 1982).

**PROPERTIES**

Direct Black 38 is a gray-black powder. It is soluble in water, moderately soluble in ethanol and ethylene glycol monoethyl ether, and insoluble in other organic solvents. When heated to decomposition, Direct Black 38 emits toxic fumes of nitrogen oxides (NO<sub>x</sub>) and sulfur oxides (SO<sub>x</sub>). The benzidine content of domestically produced Direct Black 38 has been found to range from 2 to 20 mg/kg; benzidine content of imported samples ranged from 2 to 1254 mg/kg. Another product was found to contain < 0.1 mg/kg benzidine, 150 mg/kg 4-aminobiphenyl, and 9,200 mg/kg 2,4-diaminoazobenzene. The composition of commercial Direct Black 38 varies in order to meet individual shade and intensity requirements.

## USE

Direct Black 38 is possibly being used to dye fabric, leather, cotton, cellulosic materials, and paper, which then are used in consumer products. According to CPSC and EPA, artists also may use the chemical. FDA indicated that Direct Black 38 is identified in the literature as a hair dye component, but it is not presently used by the cosmetic industry. After a health hazard alert issued by OSHA cautioning workers and employers about the carcinogenic effect of benzidine-derived Direct Black 38, researchers developed new non-benzidine Direct Black dyes. The paper and leather industries recently have used these new dyes with success in commercial applications. The nonbenzidine dyes were developed with the prospect of replacing benzidine-based dyes throughout the industry. Direct Black 38 can also be used to print cellulose, wool, and silk; to dye plastics, vegetable-ivory buttons, and wood flour used as a resin filler; to stain textiles, typewriter ribbon, wood, and biological materials; and to produce aqueous inks (NIOSH 24, 1978).

## PRODUCTION

Direct Black 38 is currently manufactured by one U.S. company (HSDB, 1998); however, no suppliers of the compound were named in *Chemycyclopedia 98* and the 1998 *Chemical Buyers Directory* (Rodnan, 1997; Tilton, 1997). In 1984 Chem Sources USA identified only one supplier of Direct Black 38 (Chem Sources, 1984). The United States imported 147,800 lb in 1983, although U.S. manufacturers have stated that they have discontinued the use of benzidine-based dyes (USITCa, 1984). The USITC last identified a single producer of Direct Black 38 in 1981, but no production volume was reported (USITC, 1982). In 1978, one manufacturer produced more than 824,000 lb of Direct Black 38 (NIOSH Review, 1980). The 1979 TSCA Inventory identified two companies producing 6 million lb of Direct Black 38 and four companies importing 555,000 lb in 1977. The CBI Aggregate was between 1 million and 10 million lb (TSCA, 1979). No data on exports were available. Direct Black 38 was first produced in commercial quantities in the United States in 1914 (IARC V.29, 1982).

## EXPOSURE

The primary routes of potential human exposure to Direct Black 38 are inhalation, ingestion, and dermal contact. Consumer exposure to Direct Black 38 depends upon the ability of the dye to migrate out of consumer products and either penetrate the skin or to degrade prior to penetrating the skin. No data quantifying the rate of migration or degradation of this dye are currently available. In the general population, unspecified exposure levels may possibly occur through the use of dyed textile products and of retail packaged dyes for home dyeing and school use. The National Occupational Hazard Survey, conducted by NIOSH from 1972 to 1974,

estimated that about 16,000 workers were possibly exposed to Direct Black 38 in the workplace, including dyers of leather, plastics, cotton, wool, and silks, along with makers of aqueous inks, biological stains, typewriter ribbons, and wood stains (NIOSH, 1976). In a more recent occupational hazard review, NIOSH estimated that approximately 13,000 workers were potentially exposed to Direct Black 38 in the workplace (NIOSH Review, 1980). The National Occupational Exposure Survey (1981-1983) estimated that 10,542 workers, including 5,820 women, were potentially exposed to the compound (HSDB, 1998). Direct Black 38 has been detected in the workplace air of a paper dyeing facility, at total airborne particulate levels of 1.6-5.1 mg/m<sup>3</sup> (0.05-0.16 ppm), and of a textile dyeing facility, at unspecified concentrations (IARC V.29, 1982).

## REGULATIONS

In 1980, CPSC collected scientific and economic data to propose a ban on the use of all benzidine congener dyes in consumer dye products. CPSC also completed studies on the dermal penetration of two of these dyes, and noted no dermal penetration. The use of benzidine congener dyes in consumer dyeing products and commercial textile application has been voluntarily decreased. Therefore, CPSC voted to deny the petition that requested a ban of these consumer dye products. Educational materials have been developed to warn artists of the potential hazard of benzidine congener dyes.

EPA subjects Direct Black 38 to reporting requirements under the Superfund Amendments and Reauthorization Act (SARA) and the Toxic Substances Control Act (TSCA). FDA does not regulate cosmetic use of Direct Black 38, but was petitioned to approve Direct Black 38 for use as an indirect food additive (e.g., as a dye for paper and paperboard products); in 1979, the petition was withdrawn. OSHA regulates Direct Black 38 under the Hazard Communication Standard and as a chemical hazard in laboratories. Regulations are summarized in Volume II, Table A-23